

Claims

1. A method for diagnosing an oral disease in a patient, comprising:
 - a. obtaining a biological sample from a patient at the point of care;
 - 5 b. determining the expression level of a plurality of genes associated with an oral disease in the biological sample, thereby producing a test expression profile;
 - c. comparing the test expression profile with at least one signature expression profile of the plurality of genes indicative of an oral disease;
 - 10 wherein if the test expression profile substantially matches a signature expression profile indicative of an oral disease, the patient has the oral disease.
- 15 2. The method of claim 1, wherein the expression level is protein expression level.
3. The method of claim 2, wherein proteins are isolated from the biological sample before their expression levels are determined.
- 20 4. The method of claim 2 or 3, wherein the protein level is determined by a method selected from: immunoassay, protein array and single molecule detection.
- 25 5. The method of claim 1, wherein the expression level is mRNA expression level.

6. The method of claim 5, wherein nucleic acids are isolated from the biological sample before their expression levels are determined.
- 5 7. The method of claim 5 or 6, wherein the mRNA level is determined by a method selected from: microarray analysis, multiplex PCR analysis and single molecule detection.
- 10 8. The method of claim 1, wherein the oral disease is oral cancer and the plurality of genes are the 45 genes of which a signature expression profile is indicative of oral cancer.
- 15 9. The method of claim 1, wherein the oral disease is oral cancer and the plurality of genes are a subset of the 45 genes of which a signature expression profile is indicative of oral cancer.
- 20 10. The method of claim 1, wherein the biological sample is selected from: saliva, tissue, bone marrow aspirates, bone marrow biopsies, lymph node aspirates, lymph node biopsies, serum, and fine needle aspirates.
11. The method of claim 1, wherein the oral disease includes oral cancer, HIV, tooth decay, gingivitis, pyorrhea, and periodontitis.
- 25 12. A method of allowing a dentist to provide for detection of oral disease at the point of patient care, comprising:
 - a. obtaining a biological sample from a dental patient at the point of care;

- b. determining the expression level of a plurality of genes associated with an oral disease in the biological sample, thereby producing a test expression profile;
 - c. comparing the test expression profile with at least one signature expression profile of the plurality of genes indicative of an oral disease; and
 - d. notifying the patient the results of the test.
13. The method of claim 12, wherein the expression level is protein expression level.
14. The method of claim 13, wherein proteins are isolated from the biological sample before their expression levels are determined.
15. The method of claim 14, wherein the expression level is mRNA expression level.
16. The method of claim 15, wherein nucleic acids are isolated from the biological sample before their expression levels are determined.
17. The method of claim 15 or 16, wherein the mRNA level is determined by a method selected from: microarray analysis, multiplex PCR analysis and single molecule detection.

18. The method of claim 12, wherein the oral disease is oral cancer and the plurality of genes are 45 genes of which a signature expression profile is indicative of oral cancer.
- 5 19. The method of claim 12, wherein the oral disease is oral cancer and the plurality of genes are a subset of the 45 genes of which a signature expression profile is indicative of oral cancer.
- 10 20. The method of claim 12, wherein the sample is selected from: saliva, tissue, bone marrow aspirates, bone marrow biopsies, lymph node aspirates, lymph node biopsies, serum, and fine needle aspirates.
- 15 21. The method of claim 12, wherein the oral disease includes oral cancer, HIV, tooth decay, gingivitis, pyorrhea, and periodontitis.
- 20 22. The method of claim 12, wherein comparing determined expression levels includes allowing the dentist to select from among a plurality of groups of known oral diseases.
- 25 23. The method of claim 12, further including obtaining authorization representative of insurance coverage.
24. The method of claim 23, further comprising selecting a test for an oral disease as a function of insurance coverage.

25. The method of claim 24, further comprising requesting insurance reimbursement for the test.
- 5 26. The method of claim 25, further comprising generating a medical record representative of the test and result.
27. A system for allowing a dentist to test for an oral disease at the point of care, comprising:
- 10 a. a sample collection device for collecting a sample from a dental patient at the point of care;
- b. a diagnostic system for generating a test expression profile by determining the expression level of a plurality of genes associated with an oral disease in the sample, and comparing the test expression profile with at least one signature expression signatures profile
- 15 c. a notification system for notifying the patient the results of the test.
28. The system of claim 27, wherein the diagnostic system comprises a micro-fluidic processing system for determining the expression level of a plurality
- 20 of genes associated with an oral disease in the sample.
29. The system of claim 28, further comprising means for allowing the dentist to select from a group of tests associated with oral diseases.
- 25 30. The system of claim 29, wherein the oral disease is oral cancer.
31. An oral disease detection kit, comprising:

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- a. a sample collection device for collecting a sample from a patient at the point of care; and
 - b. a sample delivery device, adapted for use with the system of claim 27 and being capable of delivering the sample into the system to thereby examine the sample for an indication of an oral disease.

32. The kit of claim 30, wherein the oral disease is oral cancer.